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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,392	11/12/1999	TAKASHI AOYAMA	2312-105	9249

6449 7590 02/10/2003

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/10/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.

09/438,392

Applicant(s)

Aoyama et al

Examiner

Jane Zara

Art Unit

1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 20, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-83 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-75 and 77-83 is/are rejected.
- 7) ☒ Claim(s) 76 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1635

DETAILED ACTION

Applicant's response filed 12-20-02 have been received and entered.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments and Amendments

Applicant's arguments with respect to claims 67-83 have been considered but are moot in view of the new ground(s) of rejection.

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

Art Unit: 1635

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-75, 77-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louvion et al in view of Goff et al, the combination further in view of the combined teachings of Aoyama et al, Brasselman et al and Schena et al, Draper et al and Krebbers et al.

217 218
The claimed invention is drawn to a vector or isolated nucleic acid construct (and transgenic plants or plant cells comprising the nucleic acid construct), comprising an inducible transcription construct or system which controls the expression of an operably linked gene such as a selectable marker or reporter gene including luciferase or maize LC, or a gene which can promote shoot regeneration, which inducible transcription system comprises, from 5' to 3', a constitutive or inducible promoter, nucleic acid encoding a DNA binding domain of LexA, nucleic acid encoding a VP16 transactivating domain, DNA encoding a regulatory domain of an estrogen receptor.

Louvion et al teach vectors comprising DNA sequences, from 5' to 3', encoding a constitutive promoter operably linked to a DNA binding domain of Gal 4, DNA encoding the transactivating domain of VP16, and DNA encoding the regulatory domain of an estrogen receptor (see especially figure 1 on page 130; text and Table I on page 131).

Art Unit: 1635

Louvion et al do not teach the Lex A DNA binding domain in an inducible transcription system, nor the operable linkage of nucleic acids encoding a gene which causes anthocyanin production such as maize LC, nor genes whose expression promotes shoot regeneration.

2/28/21
Goff et al teach the flexibility of gene control by utilizing DNA binding domains and response elements from a variety ^{of} ~~of~~ transcriptional activators, including the interchanging of ^{LexA} ~~sexA~~ with GAL4, in combination with VP16 as a transcriptional activator. Goff et al generally teach the use of LexA or GAL4 DNA binding sites in combination with VP16 and a mammalian steroid hormone receptor binding domain, including the estrogen receptor binding domain, in an inducible transcription systems in plants. Goff et al teach vectors and isolated nucleic acids comprising a chemically inducible promoter, and further comprising a regulatory domain of a glucocorticoid and/or an estrogen receptor, a selectable marker such as an antibiotic or a herbicide resistant gene, a CaMV 35S promoter, the DNA-binding domain and upstream activating region of GAL4, DNA encoding the VP16 transactivating domain, the DNA binding domain of the LexA repressor, nucleic acids encoding luciferase and a gene of interest (See entire document, especially col. 1-3 and 9-14, and claims 1, 12 and 15).

Aoyama et al teach nucleic acid constructs in transgenic plants comprising an inducible transcription system controlling an operably linked reporter gene (luciferase), which transcription system comprises a constitutive or inducible promoter, the DNA binding domain of GAL4, the transactivating domain of VP16 and the receptor domain of the mammalian hormone

Art Unit: 1635

glucocorticoid (see especially the text on page 605, figure 1 on page 606, text on page 608: i.e. section entitled *Responses to various glucocorticoids* and the experimental procedures described on page 610).

Brasemann et al teach an inducible transcription system comprising the DNA binding domain of GAL4, the transactivating domain of VP16, and the hormone binding domain of the estrogen receptor, and the application of such a mammalian hormone transcription induction system in cell types which do not express endogenous estrogen receptors, and which lack GAL4 binding activity (see the abstract and last two paragraphs of the introduction on page 1657, figure 1 on page 1658, figure 2 on page 1658, figure 5 on page 1660, and the text on pages 1660-1661).

Krebbers et al teach the expression and use of anthocyanin genes, including a nucleic acid encoding maize LC, for maintaining male sterility in plants (see especially the abstract, col 2-7, claim 1).

Draper et al teaches the expression of genes which can promote shoot regeneration, which genes include cell type specific, inducible promoters, which promoters are used in combination with marker genes to promote cell type specific expression in transgenic plants and high expression in plant cultures (see especially the abstract and examples 7-8, cols 23-25).

It would have been obvious to modify the vector of Louvian et al by exchanging the GAL4 binding domain with a lexA binding domain because the interchanging of these binding domains in transcription systems, and in combination with VP16, had been taught previously by Goff. One of ordinary skill in the art would have been motivated to utilize either GAL4 or lexA in

Art Unit: 1635

combination with VP16 as a transcriptional activator because it had been taught previously that the swapping of response elements and binding domains provides increased flexibility in controlling gene expression, as taught previously by Goff (see especially col. 9, lines 16-32). One of ordinary skill in the art would have expected to successfully utilize the combination of these components (e.g. either GAL4 or LexA in combination with VP16) in a transcription system because such routine exchanges had been taught previously by others in the art, including Goff. It would have been obvious to one of ordinary skill in the art to design and utilize an inducible transcription system in plants comprising a (constitutive or inducible) promoter, DNA encoding the GAL4 or LexA DNA binding domain, the VP16 transactivating domain and DNA encoding the regulatory domain of an estrogen receptor because inducible transcription systems comprising mammalian hormone regulatory domains in combination with either LexA or GAL4 binding sites and further comprising a VP16 transactivating domain have been utilized in various plant and animal cells which do not express endogenous hormone receptors, nor endogenous GAL4 or LexA activity, as taught previously by Louvion et al, Aoyama et al and Braselmann et al. One of ordinary skill in the art would have expected that a nucleic acid construct encoding, from 5' to 3', a constitutive promoter operably linked to a DNA binding domain of Gal 4 or LexA, DNA encoding the transactivating domain of VP16, and DNA encoding the regulatory domain of an estrogen receptor would provide for higher induction and expression of operably linked nucleic acid sequences encoding a marker gene because such increases in induction using this expression system have been taught previously by Louvion et al. One of ordinary skill in art would have been

Art Unit: 1635

motivated to design and utilize such a transcription induction system because host cells lacking either endogenous hormone receptors or endogenous GAL4 or LexA activity have been found to have low basal expression of genes operably linked to the transcription system, and the combination of the DNA binding site, the hormone regulatory domain and the VP16 transactivation domain has been found to generate highly inducible gene products in appropriate plant and animal host cells, as taught previously by Aoyama et al and Braselmann et al. One of ordinary skill in the art would have expected that such highly inducible transcription systems would provide high levels of expression of operably linked nucleic acids, including reporter or selection genes such as antibiotic resistance genes or luciferase. One of ordinary skill in the art would have been motivated to operably link a nucleic acid encoding a gene causing anthocyanin production because anthocyanin production provides a color phenotype for selecting transformed plants or plant cells harboring a gene causing its production, as taught previously by Krebbers et al. One of ordinary skill in the art would have been motivated to induce the transcription of a gene which promotes shoot regeneration because such genes are utilized for cell type specific expression of operably linked genes, or for increased expression of operably linked genes in plant tissue culture, as taught previously Draper et al.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1635

Allowable Subject Matter

Claim 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

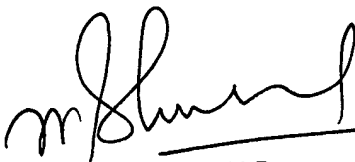
Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a

Art Unit: 1635

general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


RAM R. SHUKLA, PH.D
PATENT EXAMINER

JZ

February 7, 2003